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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,069

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EXAMINER

KWAK, JAE J

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,069	<b>Applicant(s)</b> ALMEN ET AL.	
	<b>Examiner</b> JAE KWAK	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 18-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/04/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I claims 1-17, and 42 in the reply filed on 02/27/2009 is acknowledged. Claims 18-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/27/2009.

### *Claim Objections*

2. Claims 13 and 15 are objected to because of the following informalities: Recited acronym (**BMP**) needs to be defined in claims. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9, 10, 11, 12, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding to Claim 9: The Claim 9 recites the limitation "within the polymer" in line 5. There is insufficient antecedent basis for this limitation in the claim. The recitation "within the polymer" renders the claim indefinite because it is unclear to what polymer reference is made. In claim 1, the only polymer is the particulate polymer portion. However, it seems "the polymer" of line 5 does not refer to this since comparison is made between "the polymer" and

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the particulate polymer. It appears that monomers of the liquid portion are polymerized.

However, if this is the case, the monomer would be no longer present and the dependent claim would not have all the limitations of the independent claim. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For purpose of further examination, examination is precluded with respect to this limitation until it is clarified.

Regarding claims 10-11: Claim 10 recites the limitation "within the polymer" in line 5 and also line 3 in claim 11. There is insufficient antecedent basis for this limitation in the claim. The recitation "within the polymer" renders the claim indefinite because it is unclear to what polymer either particle portion or liquid portion does organoiodine compound is referring. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For purpose of further examination, examination is precluded with respect to this limitation until it is clarified.

Regarding to Claim 12: The Claim 12 recites that organoiodine compound is a "cross-linking agent" in line 3 which renders the claim indefinite because the organoiodine compound refer to claim 1 is "non-polymerizable" therefore it is indefinite how an organoiodine compound be a cross-linking agents are known to react in the polymerization step.

Regarding to Claim 42: The Claim 42 recites the limitation "within the polymer" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim. The recitation "within the polymer" renders the claim indefinite because it is unclear to what polymer either particle portion or liquid portion does organoiodine compound is referring. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For purpose of further examination, examination is precluded with respect to this limitation until it is clarified.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4, 5, 6, 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US Patent 6,586,009) in view of Koole (US Patent 6,040,408).

Regarding claim 1: Lidgren teaches bone cement (Col. 2 line 43) composition comprising a liquid component of polymerizable substances/monomer (Claim 1) and a powder component/particular polymer (Claim 1) having an iohexol/non-polymerizable organoiodine compound (Example 1, line9). Lidgren is silent on liquid component having organoiodine component. However, Koole teaches polymer of a monomer molecule that is covalently-linked iodine (Col. 1 line 29), such as iodine-containing substituent such as [NH-CH<sub>2</sub>-CH<sub>2</sub>-O-C(O)-C<sub>6</sub>H<sub>2</sub>I<sub>3</sub>] See Col. 2 line 17. Lidgren and Koole are analogous art because they are both concerned with same field of endeavor, namely an iodine polymer application for bone cements. At the time of invention a person having ordinary skill in art would have found it obvious to combine the iodine containing polymer taught by Koole with polymer powder component of Lidgren and motivated to do so for such desirable properties to improve mechanical polymer composition and visibility during X-ray scanning applications.

Regarding claim 4: Lidgren is silent on a chemically homogenized distribution. However, Koole teaches a bone cement (Col. 1 line 10) solution component are continuously

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stirred/distributed homogeneously (Col. 3 lines 50-53). At the time of invention a person having ordinary skill in art would have found it obvious to combine the mixing iodine-containing monomer with other reactive monomer taught by Koole with polymer powder component of Lidgren and motivated to do so for such desirable properties to improve mechanical polymer composition and evenly distributing the bone cement compositions.

Regarding claim 5: Lidgren teaches X-ray contrast medium/X-ray contrast agent (Col. 2 line 65) such as iohexol (Col. 2 line 67).

Regarding claim 6: Lidgren teaches an antibiotic substance (Example 4) is added to bone cement composition.

Regarding claim 16: Lidgren teaches particles powder with a diameter a 4  $\mu\text{m}$  with polymer having a 80-100  $\mu\text{m}$  (Example 1 line 15).

Regarding claim 17: Lidgren teaches water soluble non-ionic powdered component such as iohexol (Col. 2 line 65-68). Since only iohexol makes up the particles they are polydisperse with regards to the powder component.

7. Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koole (US Patent 6,040,408) in view of Vazquez et al ("Radiopaque acrylic cement prepared with a new acrylic derivative of iodo-quinoline" Biomaterials 1999 Pg 2047-2053)

Regarding claim 2: Koole teaches iodine containing monomer molecules/liquid portion such as (4-iodophenyl) methacrylate (Col. 2 line 35, Example 1). Koole is silent on particulate polymer portion comprising organoiodine compound. However Vazquez et al. teaches incorporating acrylic radiopaque cements comprising 2,5-diiodo-8quinoly methacrylate

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(abstract) compound to the liquid phase (Page 2053 Col. 1 paragraph 3) Koole and Vazques et al. are analogous art because they are both concerned with same field of endeavor, namely, bone cement composition comprising iodine molecules. At the time of invention a person having ordinary skill in art would have found it obvious to combine the acrylic radiopaque cement compound into iodine containing monomer molecules taught by Koole and motivated to do so for such desirable properties to improve tensile and biocompatibility of iodine containing polymeric compositions.

8. Claims 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koole (US Patent 6,040,408) in view of Vazquez et al ("Radiopaque acrylic cement prepared with a new acrylic derivative of iodo-quinoline" Biomaterials 1999 Pg 2047-2053)

Regarding claim 3: Koole teaches iodine containing monomer molecules/liquid portion such as (4-iodophenyl) methacrylate (Col. 2 line 35, Example 1). Furthermore, Koole teaches during the reaction an amide bond (Col 2 line 60) is generated for iodine monomer compound. Koole is silent on particulate polymer portion comprising organoiodine compound. However Vazquez et al. teaches incorporating acrylic radiopaque cements comprising 2,5-diiodo-8-quinolyl methacrylate (abstract) compound to the liquid phase (Page 2053 Col. 1 paragraph 3) Koole and Vazques et al. are analogous art because they are both concerned with same field of endeavor, namely, bone cement composition comprising iodine molecules. At the time of invention a person having ordinary skill in art would have found it obvious to combine the acrylic radiopaque cement compound into iodine containing monomer molecules taught by Koole and

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motivated to do so for such desirable properties to improve tensile and biocompatibility of iodine containing polymeric compositions.

9. Claims 6, 7, 8, 12, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren as applied to claim 1 above, and further in view of Nies et al. (US Patent 5,650,108)

Regarding claims 6, 7, 8: Lidgren and Koole teach the basic claimed compositions as set forth above and also Lidgren teaches antibiotic substance is added to the iodine powder component (Example 4). Lidgren is silent on the specific antibiotic compound and amounts. However, Nies et al. teaches clindamycin antibiotic compound (Col. 5 line 29) which reads on as lipophilic ester antibiotic compound. Lidgren and Nies et al. are analogous art because they are both concerned with same field of endeavor, namely bone cement compositions comprising antibiotic compounds. At the time of invention a person having ordinary skill in art would have found it obvious to substitute specific antibiotic compounds such as the clindamycin into polymer powder component of Lidgren and motivated to do so for such desirable properties to improve prolong biocide characteristics of bone cement polymer compositions.

Regarding claim 12: Lidgren teaches a iohexol/organoiodine compound (Example 1) with 2-3 part of mixed with 10 part of polymer which reads on as claimed amount. Since claim recites that organoiodine compound is cross-linking agent the iohexol would have same property

Regarding claim 14: Lidgren is silent on the amount of liquid portion. However, Nies et al. teaches one of components in bone cement comprises 2 to 50% by weight of liquid component (b). See (Col. 3 line 32) which reads on the instant claimed amount. At the time of invention a person having ordinary skill in art would have found it obvious to substitute specific



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amounts of liquid monomer with the polymer powder of Lidgren and motivated to do so for such desirable properties to improve a mechanical strength of bone cement compositions.

10. Claims 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren as applied to claim 1 above, and further in view of Lautenschlafer et al. (US Patent 5,902,839).

Regarding claim 13, 15: Lidgren and Koole teach the basic claimed compositions as set forth above in paragraph 6. Lidgren is silent on liquid portion comprising a hydroquinone. However, Lautenschlager et al. teaches bone cement composition (abstract) with liquid polymer component having a hydroquinone (Claim 16). Lidgren and Lautenschlager et al. are analogous art because they are both concerned with same field of endeavor, namely bone cement compositions comprising radiopaque/X-ray contrast material. At the time of invention a person having ordinary skill in art would have found it obvious to combine hydroquinone with liquid polymer component of Lidgren and motivated to do so for such desirable properties to inhibit spontaneous polymerization.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAE KWAK whose telephone number is (571)270-7339. The examiner can normally be reached on Monday to Friday 8:30 A.M. EST 5:30 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.K.

/Mark Eashoo/  
Supervisory Patent Examiner, Art Unit 1796